

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

, Individually and On Behalf of All Others Similarly Situated, Plaintiff, v. GENOCEA BIOSCIENCES, INC., WILLIAM D. CLARK, and JONATHAN POOLE, Defendants.	}	Case No. <u>CLASS ACTION COMPLAINT</u> <u>JURY TRIAL DEMANDED</u>
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CLASS ACTION COMPLAINT

Plaintiff (“Plaintiff”), individually and on behalf of all other persons similarly situated, by his undersigned attorneys, for his complaint against Defendants, alleges the following based upon personal knowledge as to himself and his own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through his attorneys, which included, among other things, a review of the Defendants’ public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission (“SEC”) filings, wire and press releases published by and regarding Genoccea Biosciences, Inc. (“Genoccea” or the “Company”), analysts’ reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons other than Defendants who purchased or otherwise acquired Genoccea securities between

May 5, 2017 and September 25, 2017, both dates inclusive (the “Class Period”), seeking to recover damages caused by defendants’ violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”) and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. Genoccea is a biopharmaceutical company that discovers and develops vaccines and immunotherapies. At all relevant times, Genoccea’s genital herpes immunotherapy product GEN-003 was the Company’s lead product candidate.

3. Founded in 2006, the Company is headquartered in Cambridge, Massachusetts. Genoccea’s stock trades on the NASDAQ Capital Market (“NASDAQ”) under the ticker symbol “GNCA.”

4. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company’s business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the Company’s finances were insufficient to support Phase 3 trials of GEN-003; (ii) accordingly, Genoccea had overstated the prospects for GEN-003; and (iii) as a result of the foregoing, Genoccea’s public statements were materially false and misleading at all relevant times.

5. On September 25, 2017, post-market, Genoccea disclosed that it was halting spending and activities on GEN-003 and exploring strategic alternatives for the drug. The Company also announced that it was cutting 40% of its workforce.

6. On this news, the Company’s share price fell \$4.08, or 76.5%, to close at \$1.25 on September 26, 2017.

7. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

8. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and Section 27 of the Exchange Act.

10. Venue is proper in this Judicial District pursuant to §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1391(b). Genoclea's principal executive offices are located within this Judicial District.

11. In connection with the acts, conduct and other wrongs alleged in this Complaint, defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

PARTIES

12. Plaintiff, as set forth in the attached Certification, acquired Genoclea securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

13. Defendant Genoclea is incorporated in Delaware, with principal executive offices located at 100 Acorn Park Drive, Cambridge, Massachusetts 02140. Genoclea's shares trade on the NASDAQ under the ticker symbol "GNCA."

14. Defendant William D. Clark (“Clark”) has served at all relevant times as the Company’s Chief Executive Officer (“CEO”) and President.

15. Defendant Jonathan Poole (“Poole”) has served at all relevant times as the Company’s Chief Financial Officer (“CFO”).

16. The defendants referenced above in ¶¶ 14-15 are sometimes referred to herein as the “Individual Defendants.”

SUBSTANTIVE ALLEGATIONS

Background

17. Genoclea develops novel vaccines and immunotherapies to address diseases with significant unmet needs. The Company uses its proprietary discovery platform, ATLAS™, to design vaccines and immunotherapies that act, in part, through T cell (or cellular) immune responses, in contrast to approved vaccines and immunotherapies, which are designed to act primarily through B cell (or antibody) immune responses.

18. At all relevant times, until September 26, 2017, Genoclea’s genital herpes immunotherapy product GEN-003 was the Company’s lead product candidate.

Materially False and Misleading Statements Issued During the Class Period

19. The Class Period begins on May 5, 2017, when Genoclea filed a quarterly report on Form 10-Q with the SEC, announcing the Company’s financial and operating results for the quarter ended March 31, 2017 (the “Q1 2017 10-Q”). In the Q1 2017 10-Q, the Company stated, in relevant part:

The Company expects that existing cash, cash equivalents and investments are sufficient to support operating expenses, capital expenditure requirements, and debt obligations into the first quarter of 2018, without assuming any receipt of proceeds from potential business development partnerships or equity financings. This guidance assumes the Company commences a Phase 3 clinical trial for GEN-003 for genital herpes around the end of 2017 . . . ; however, it is the Company’s

strategy to secure additional sources of financing in advance of starting GEN-003 Phase 3 clinical trials.

Our lead program is GEN-003, a Phase 2 candidate therapeutic vaccine, or immunotherapy, that we are developing to treat genital herpes infections. We have completed two positive clinical trials and have a third clinical trial currently underway which has also demonstrated positive interim efficacy results.

In December 2015, a Phase 2b clinical trial was initiated as our first study testing potential Phase 3 endpoints with a Phase 3-ready formulation of GEN-003, manufactured with commercially-scalable processes.

In September 2016, we announced positive viral shedding rate reductions from the ongoing Phase 2b study. The study achieved its primary endpoint . . .

In January 2017, we announced further positive clinical results from the ongoing Phase 2b clinical trial.

Around the end of the first quarter of 2017, we had a successful end-of-Phase 2 meeting with the FDA, the outcome of which was aligned with our previously disclosed Phase 3 design expectations. We continue to expect that GEN-003 will be Phase 3-ready in the fourth quarter of 2017. We plan to commence a clinical trial exploring the potential additive effects of GEN-003 on top of daily administration of valacyclovir in parallel with the Phase 3 program. We retain all rights to GEN-003 and if GEN-003 successfully completes clinical development and is approved, we believe it would represent an important new treatment option for patients with genital herpes.

20. The Q1 2017 10-Q contained signed certifications pursuant to the Sarbanes-Oxley Act of 2002 (“SOX”) by the Individual Defendants, stating that the financial information contained in the Q1 2017 10-Q was accurate and disclosed any material changes to the Company’s internal control over financial reporting.

21. On July 24, 2017, the Company issued a press release entitled, “Genocea Reports Positive Top-Line 12-Month Phase 2b Data for GEN-003 in Genital Herpes,” gave a presentation

to investors regarding the positive clinical results for the 12-month analysis of the Company's Phase 2b trial of GEN-003, and filed an 8-K attaching the press release and presentation as exhibits. In the press release, the Company stated in part:

In this 131-subject Phase 2b clinical trial, GEN-003 reduced the median genital lesion rate (or percent days with genital lesions) versus placebo by 49 percent (p=0.01) over the 12 months' post dosing at the 60 μ g per antigen / 50 μ g of adjuvant dose. Importantly, these results were achieved at the Phase 3 dose and expected Phase 3 primary endpoint. Other clinical endpoints for this dose improved or were consistent with previously reported positive data. No changes were observed to the previously established safety profile of GEN-003.

22. On August 9, 2017, Genoceia filed a quarterly report on Form 10-Q with the SEC, announcing the Company's financial and operating results for the quarter ended June 30, 2017 (the "Q2 2017 10-Q"). In the Q2 2017 10-Q, the Company stated, in relevant part:

In June and September 2016, the Company entered into new statements of work under the agreement with Fujifilm for the manufacture and supply of antigens for the Company's Phase 3 clinical trials for GEN-003.

In July 2017, we announced positive clinical results from the Phase 2b trial. At twelve months after dosing, GEN-003 demonstrated statistically significant improvements versus placebo in both the median genital lesion rate and across multiple clinical endpoints. Importantly, these results were achieved at the Phase 3 dose and expected Phase 3 primary endpoint.

In our planned Phase 3 trial, we expect to have a much larger sample size from the hundreds of patients from whom we plan to collect viral shedding samples, and we believe that this larger sample size may lead to greater differentiation in viral shedding in GEN-003 subjects versus placebo.

Around the end of the first quarter of 2017, we had a successful end-of-Phase 2 meeting with the U.S Food and Drug Administration or FDA, the outcome of which was aligned with our previously disclosed Phase 3 design expectations.

23. The Q2 2017 10-Q contained signed certifications pursuant to SOX by the Individual Defendants, stating that the financial information contained in the Q2 2017 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

24. The statements referenced in ¶¶ 19-23 were materially false and misleading because defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operational and compliance policies. Specifically, defendants made false and/or misleading statements and/or failed to disclose that: (i) the Company's finances were insufficient to support Phase 3 trials of GEN-003; (ii) accordingly, Genoceca had overstated the prospects for GEN-003; and (iii) as a result of the foregoing, Genoceca's public statements were materially false and misleading at all relevant times.

The Truth Begins to Emerge

25. On September 25, 2017, *post-market*, Genoceca issued a press release entitled "Genoceca Announces Strategic Shift to Immuno-oncology and the Development of Neoantigen Cancer Vaccines," announcing that it was halting spending and activities on its lead product GEN-003. The press release stated, in relevant part:

Genoceca Biosciences, Inc. (NASDAQ: GNCA), a biopharmaceutical company discovering and developing novel vaccines and immunotherapies targeting T cell antigens, today announced a strategic shift to immuno-oncology and a focus on the development of neoantigen cancer vaccines, including GEN-009, its lead candidate for which it expects to file an Investigational New Drug (IND) application by early 2018. Genoceca also announced it is exploring strategic alternatives for GEN-003, its Phase 3-ready investigational immunotherapy for the treatment of genital herpes. Consequently, ***Genoceca is ceasing GEN-003 spending and activities and is reducing its workforce by approximately 40 percent.***

(Emphasis added.)

26. On this news, the Company's share price fell \$4.08, or 76.5%, to close at \$1.25 on September 26, 2017.

27. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

28. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Genocsea securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest.

29. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Genocsea securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Genocsea or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

30. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by defendants' wrongful conduct in violation of federal law that is complained of herein.

31. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

32. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by defendants' acts as alleged herein;
- whether statements made by defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Genocera;
- whether the Individual Defendants caused Genocera to issue false and misleading financial statements during the Class Period;
- whether defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of Genocera securities during the Class Period were artificially inflated because of the defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

33. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually

redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

34. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Genocsea securities are traded in an efficient market;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiff and members of the Class purchased, acquired and/or sold Genocsea securities between the time the defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

35. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

36. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

37. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

38. This Count is asserted against defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

39. During the Class Period, defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Genocsea securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Genocsea securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, defendants, and each of them, took the actions set forth herein.

40. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to

influence the market for Genoccea securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Genoccea's finances and business prospects.

41. By virtue of their positions at Genoccea, defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to defendants. Said acts and omissions of defendants were committed willfully or with reckless disregard for the truth. In addition, each defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

42. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within defendants' knowledge and control. As the senior managers and/or directors of Genoccea, the Individual Defendants had knowledge of the details of Genoccea's internal affairs.

43. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Genoccea. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Genoccea's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements,

the market price of Genocea securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Genocea's business and financial condition which were concealed by defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Genocea securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by defendants, and were damaged thereby.

44. During the Class Period, Genocea securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Genocea securities at prices artificially inflated by defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Genocea securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Genocea securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

45. By reason of the conduct alleged herein, defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

46. As a direct and proximate result of defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases,

acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against The Individual Defendants)

47. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

48. During the Class Period, the Individual Defendants participated in the operation and management of Genocsea, and conducted and participated, directly and indirectly, in the conduct of Genocsea's business affairs. Because of their senior positions, they knew the adverse non-public information about Genocsea's misstatement of income and expenses and false financial statements.

49. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Genocsea's financial condition and results of operations, and to correct promptly any public statements issued by Genocsea which had become materially false or misleading.

50. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Genocsea disseminated in the marketplace during the Class Period concerning Genocsea's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Genocsea to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of Genocsea within the meaning of Section 20(a) of the Exchange Act. In this capacity, they

participated in the unlawful conduct alleged which artificially inflated the market price of Genoccea securities.

51. Each of the Individual Defendants, therefore, acted as a controlling person of Genoccea. By reason of their senior management positions and/or being directors of Genoccea, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Genoccea to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Genoccea and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

52. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Genoccea.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

- A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;
- B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;
- C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and
- D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.